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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/816,697	03/23/2001	Meike Lorenz	GFN-5380	5997

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	10

DATE MAILED: 11/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/816697	LORENZ
	Examiner	Art Unit
	GAMBEL	1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 6/25/02 / 9/3/02.

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 26-48

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 26-48

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☑ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☑ objected to by the Examiner. SEE OFFICE ACTION

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☑ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

PAPER NO. 14

Serial No. 09/816697
Art Unit 1644

DETAILED ACTION

1. Applicant's amendment, filed 9/3/02 (Paper No. 13), has been entered.
   Claims 1-25 have been canceled.
   Claim 26 has been amended.
   Claims 27-48 have been added.

   Applicant's initial election of Group VI with traverse in Paper No. 10, filed 6/25/02, is acknowledged.

   However, given the cancellation of claims 1-25 in Paper No. 13, filed , the previous Restriction Requirement set forth in Paper No. 6 is rendered moot.

   Claims 26-48 are being acted upon presently.

2. Formal drawings have been submitted which fail to comply with 37 CFR 1.84.
   Please see the enclosed form PTO-948.

   INFORMATION ON HOW TO EFFECT DRAWING CHANGES
   A. Correction of Informalities -- 37 CFR 1.85
   New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

   B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.
   All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

   Timing of Corrections
   Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 26-29, 31-35, 37-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection

The specification does not provide adequate written description of the claimed invention, for "a SLIC-1 protein" (recited in claims 26-27), "at least 90% identical to SEQ ID NO: 2" (recited in claims 31-33, 39) "comprises" "a sequence" or "at least .... contiguous amino acids of ... a sequence or a SEQ ID NO" (recited in claims 28-45" and "at least one immunoreceptor tyrosine motif" (recited in claim 46) because the relevant identifying characteristics such as structure or other physical and/or chemical characteristics of said proteins or sequences are not set forth in the specification as-filed, commensurate in scope with claimed invention.

In addition, there does not appear sufficient written description for the elements of claim 40, including (1) a protein comprising a SH2 domain, (2) intracellular domain of PSGL-1, (3) intracellular signaling molecule and (4) a cytoskeletal protein".

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Thus, the specification fails to describe these DNA sequences. The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function.

Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicant is claiming a generic class of "SLIC proteins", a generic class of SLIC-1 proteins "comprising fragments" of certain SLIC-1 proteins or a generic class of "tyrosine base motifs" based upon the support of the disclosure of a limited representative number of species (e.g. SEQ ID NO: 1 or 2).

Page 24, paragraph 4 of the instant invention discloses that the claims could encompass a number of natural allelic variants or mutants (e.g. see page 24, paragraph 4). However, it is not appear that the specification as filed provides sufficient written description of the genus of SLIC proteins other than that set forth in SEQ ID NOS: 1 and 2.

Page 24, paragraph 2 discloses that the biological active portions of a SLIC-1 protein is a fragment of SLIC-1 protein which participates in an interaction between a SLIC-1 molecule and a non-SLIC-1 molecule. In addition, this paragraph discloses that the biologically active fragments should contain domains or motifs that modulate signal transduction, PSGL association with the cytoskeleton or cell adhesion. However, it does not appear that the specification as filed has provided sufficient written description of the biologically active fragments (e.g. domains or motifs) that provide the asserted biological functions of SLIC-1 as set forth in SEQ ID NOS: 1 and 2. Again, the specification as filed does not appear to provide written description of natural allelic variants or mutants of the disclosed SLIC-1 proteins and, in turn, the biologically active fragments of said allelic variants and mutants.

It is noted that the claims drawn to claims "comprising fragments" do not recite functional language. Even if the claims did recite "biologically active fragments", it is not readily apparent that there is sufficient written description of the SLIC-1 proteins or polypeptides that "comprising at least" "a certain number of amino acids" which correlates to the disclosed functions. Furthermore, these claims recite "comprising" and there does not appear sufficient written description of the additional sequences associated with the claims SLIC-1 proteins or polypeptides that do not contain the entire protein.

In addition, it is noted that page 24, line 27 does not disclose any representative immunoreceptor tyrosine-based activation motif.

The instant specification does not provide sufficient written description as to the critical structural features of said "SLIC proteins""molecules" and the correlation between the chemical structure and the desired structural and/or function.

Applicant is relying upon certain structural and/or biological activities and the disclosure of a limited representative number of species to support entire genuses. The reliance on the disclosed limited examples of SLIC-1 as set forth in SEQ ID NOS: 1 and 2 does not support the written description of any "member" of these claimed SLIC-1 proteins and polypeptides."

Further it does not appear that the specification has provided sufficient written description of a representative number of species for the elements of claim 40, including (1) a protein comprising a SH2 domain, (2) intracellular domain of PSGL-1, (3) intracellular signaling molecule and (4) a cytoskeletal protein".

It has been well known that minor structural differences even among structurally related compounds or compositions can result in substantially different biological or pharmacological activities.

Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required

The instant specification and claims do not provide sufficient functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus / genuses, and because the genus / genuses is / are highly variable, the disclosure of the particular SLIC-1 proteins set forth in SEQ ID NOS 1 and 2 is insufficient to describe the genus of molecules, encompassed by the claimed invention.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genus or genuses of "the claimed SLIC-1 proteins and polypeptides", one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus / genuses. Thus, applicant was not in possession of the claimed genus / genuses. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

8. Claims 26-29, 31-35, 37-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "SLIC-1 set forth in SEQ ID NOS: 1 and 2" and , does not reasonably provide enablement for any "SLIC-1 protein or polypeptide" including "at least 90% identical to SEQ ID NO: 2" (recited in claims 31-33, 39) "comprises" "a sequence" or "at least .... contiguous amino acids of ... a sequence or a SEQ ID NO" (recited in claims 28-45) , encompassed by the claimed invention.

Claims 26-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "inhibiting signal transduction, association with the cytoskeleton or cell adhesion via PSGL-1", does not reasonably provide enablement for any "activity of said SLIC-1 protein", encompassed by the claimed invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.

Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) that distinctly identifies SLIC-1 proteins and polypeptides that comprise "at least 90% identical to SEQ ID NO: 2" . "comprises" "a sequence" or "at least .... contiguous amino acids of ... a sequence or a SEQ ID NO".

While "SLIC-1 protein or polypeptide" may have some notion of the structure or activity of these molecules, claiming biochemical molecules by a certain name as well as sequence identity or partial sequences fails to distinctly claim what that molecule is and what it is made up of. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable any "SLIC-1 protein or polypeptide" including "at least 90% identical to SEQ ID NO: 2" (recited in claims 31-33, 39) "comprises" "a sequence" or "at least .... contiguous amino acids of ... a sequence or a SEQ ID NO" (recited in claims 28-45"), encompassed by the claimed invention

Applicant is claiming a generic class of "SLIC proteins", a generic class of SLIC-1 proteins "comprising fragments" of certain SLIC-1 proteins or a generic class of "tyrosine base motifs" based upon the support of the disclosure of a limited representative number of species (e.g. SEQ ID NO: 1 or 2).

Page 24, paragraph 4 of the instant invention discloses that the claims could encompass a number of natural allelic variants or mutants (e.g. see page 24, paragraph 4). However, it is not appear that the specification as filed provides sufficient written description of the genus of SLIC proteins other than that set forth in SEQ ID NOS: 1 and 2.

Since the amino acid sequence of a polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar functionality requires a knowledge of and guidance with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved, and detailed knowledge of the ways in which a polypeptide's structure relates to its functional usefulness. However, the problem of predicting a polypeptide structure from the disclosure of a limited sequence or a limited number of molecules (e.g. SEQ ID NOS: 1 and 2 disclosed in the specification and claimed) and, in turn, utilizing predicted structural determinations to ascertain binding or functional aspects of the claimed SLIC-1 proteins and polypeptides and finally what changes can be tolerated with respect thereto is complex and well outside the realm of routine experimentation. Also, given the partial sequences, there appears insufficient enablement as to what can be added to the partial sequences of SEQ ID NO:1 and 2 that can provide the appropriate functional and structural requirements for SLIC-1 proteins and polypeptides to be employed in the claimed methods.

In re Fisher, 1666 USPQ 19 24 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different biological and pharmacological activities.

A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. There is insufficient guidance based on in vitro characterization assays to direct a person of skill in the art to select particular sequences as essential for the characterization of their ability to modulate signal transduction, PSGL association with the cytoskeleton or cell adhesion. A person of skill in the art could not predict which particular amino acid sequences of SEQ ID NOS: 1 and 2 of the disclosed SLIC-1 proteins are essential and could be used in the claimed screening assays.

Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) disclose that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Thus an assignment of function based upon sequence homology or identity without further functional analysis does not appear to provide sufficient enabling support for the claimed Toll homolog encoding nucleic acids and so the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

In further support for the lack of predictability in determining in structure and function Ngo et al. (in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.) disclose that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) was not well understood and was not predictable. Therefore making and using the breadth of molecules in the claimed methods would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, making and using the SLIC-1 proteins and polypeptides comprising "partial sequences of" and/or "sequences at least 90% identical to" SEQ ID NO: 1 while providing or maintaining the claimed specificity and functional characteristics of SEQ ID NOS: 1 and 2 would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Page 24, paragraph 2 discloses that the biological active portions of a SLIC-1 protein is a fragment of SLIC-1 protein which participates in an interaction between a SLIC-1 molecule and a non-SLIC-1 molecule. In addition, this paragraph discloses that the biologically active fragments should contain domains or motifs that modulate signal transduction, PSGL association with the cytoskeleton or cell adhesion. However, it does not appear that the specification as filed has provided sufficient enablement of the activity or the biologically active fragments (e.g. domains or motifs) that provide the asserted biological functions of SLIC-1 as set forth in SEQ ID NOS: 1 and 2.

Further, the specification as filed does not appear to provide enablement of natural allelic variants or mutants of the disclosed SLIC-1 proteins and, in turn, the biologically active fragments of said allelic variants and mutants that would have the same properties of SLIC-1 set forth in SEQ ID NOS: 1 and 2, including the inhibition of signal transduction, association with the cytoskeleton or cell adhesion via PSGL-1.

Applicant has not provided sufficient direction how to make and to use SLIC-1 to screen for any "activity" in order to identify compounds.

Applicant should limit the methods for identifying a compound which inhibits the activity of a SLIC-1 protein to specific and discrete endpoints such as the inhibition of signal transduction, association with the cytoskeleton or cell adhesion via PSGL-1 (or other endpoints enabled by the instant disclosure).

It is noted that the claims drawn to claims "comprising fragments" do not recite functional language. Even if the claims did recite "biologically active fragments", it is not readily apparent that there is sufficient enablement of the SLIC-1 proteins or polypeptides that "comprising at least" "a certain number of amino acids" which correlates to the disclosed functions.

The success of state of the art structure-based strategies for inhibitor design is highly unpredictable. For example, Kuntz (Science 257:1078-1082, 1992) on page 1080, column 3, discloses that as little as 2% of compounds predicted to inhibit specific enzymatic or receptor systems actually show inhibition in the micromolar range. Kuntz further discloses that "optimization" of these compounds has proven even more problematic. Therefore, in view of the unpredictability in the art, and in view of the insufficient guidance and working examples in the specification, the quantity of experimentation required by one skilled in the art to practice the invention undue.

The specification does not adequately teach how to effectively identifying a compound which inhibits "any activity" of a SLIC-1 protein including the lack of clear endpoints and the use of variants other than the SLIC-1 proteins set forth in SEQ ID NOS: 1 and 2.

Given the relative incomplete understanding in the biotechnological field involved, and the lack of a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims, a rejection under 35 USC 112, first paragraph for lack of enablement is deemed appropriate.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the modifications in SLIC-1 proteins and the lack of discrete and measurable endpoints, methods of identifying a compound which the activity of a SLIC-1 protein as claimed is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Applicant is invited to amend the claims to recite specific and measurable endpoints as well as to limit the SLIC-1 proteins to SEQ ID NOS:1 and 2.

9. Claims 40-43 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

The specification does not provide a sufficient enabling description of the claimed invention as it reads on "at least on immunoreceptor tyrosine based motif".

It is noted that page 24, line 27 does not disclose any representative immunoreceptor tyrosine-based activation motif.

Further, it does not appear that the specification has provided sufficient enablement for a representative number of species for the elements of claim 40, including (1) a protein comprising a SH2 domain, (2) intracellular domain of PSGL-1, (3) intracellular signaling molecule and (4) a cytoskeletal protein".

A person of skill in the art is not enabled to make and use "at least on immunoreceptor tyrosine based motif"" nor the elements of claim 40, as recited in the claims. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. A person of skill in the art could not predict which particular amino acid sequences of "at least on immunoreceptor tyrosine based motif" are essential and could be used in the claimed screening assays.

"It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, making and using use "at least on immunoreceptor tyrosine based motif" or the elements of claim 40 to be employed in the claimed screening methods would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

10. Claims 26-48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite in the recitation of "a method of identifying a compound which inhibits the activity of a SLIC-1 protein" because the nature and metes and bounds of said "activity" are ambiguous and ill-defined.

Applicant should amend the claims to recite clear and distinct method steps, including clear and distinct measurable activities. Also, see the rejection under 35 USC 112, first paragraph, scope of enablement above.

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

11. No claim is allowed.

It appears that the SLIC-1 protein set forth in SEQ ID NOS: 1 and 2 are free of the art. Accordingly, methods that are drawn to methods of identifying a compound which inhibits the activty of a SLIC-1 protein are free of the art.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
November 14, 2002